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(54) Introducer sheaths.

(57) A multiple lumen vascular access introducer sheath having a main lumen for introduction of another device such as a catheter therethrough and into the vascular system and a secondary lumen having a cross-sectional area significantly less than that of the main lumen for infusion of small doses of medication therethrough at a controlled rate and directly into the vascular system. The introducer sheath comprises a tubular member of an inelastic, semi-rigid plastic material such as fluorinated ethylene, propylene or nylon. The main lumen extends longitudinally through the tubular member and opens at the distal and proximal ends thereof. The secondary lumen is positioned adjacent to and separated from the main lumen with a cross-sectional area approximately fifteen percent of that of the main lumen. The distal end of the tubular member is tapered with the distal end of the secondary lumen closed. The secondary lumen has a side port near the tapered distal end. The sheath also includes a hub with main and secondary passages communicating with the main and secondary lumens of the tubular member. The longitudinal axes of the main passages are substantially parallel to one another. The secondary passage extends laterally from the secondary lumen of the tubular member which is recessed from the proximal end thereof. The hub also includes a third passage communicating with and extending laterally from the main lumen of the tubular member.

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This invention relates to introducer sheaths.

It is often desirable to maintain vascular access with a device that simultaneously accommodates multiple use such as the insertion of various devices and the injection or withdrawal of fluids. In emergency and critical care situations, urgently needed medication can be injected through the lumen of an introducer sheath, which already provides for passage of wire guides, catheters, and other devices. Injecting an emergency dose of medication through the introducer sheath at an established vascular access site eliminates the potentially life-threatening time delay of obtaining an additional site. Furthermore, a patient may not have another usable site for vascular access. Therefore, it is desirable that a vascular access introducer sheath be capable of supporting multiple applications and, in particular, simultaneously accommodating the insertion of devices and the injection of fluids, particularly at a controlled infusion rate.

Several possible solutions have been suggested for simultaneously supporting multiple applications. One solution is the use of a single-lumen introducer sheath. A problem with this introducer sheath is that the wire guide or catheter positioned through the lumen occludes the lumen and obstructs the passage of fluid through the lumen. As a result, a small amount of injected medication requires a relatively large "push" of another fluid such as saline to facilitate forcing the medication to the distal end of the sheath. A single-lumen introducer sheath can also include a side port positioned about the proximal end thereof. A proximally positioned side port provides a second avenue of entry to the introducer sheath lumen, but the above-mentioned problem with having only a single lumen remains. Another problem with the side port is that there is dead space in the side port fitting at the proximal end of the sheath lumen where medication and fluids pool. A relatively large "push" of saline dilutes the small dose of medication already backed up and remaining in the dead space. As a result, the "push" serves to force very little medication to the distal end of the sheath and into the bloodstream of a patient. There is also another major problem with single-lumen introducer sheaths, particularly when attempting to infuse medication at a controlled rate. The insertion and withdrawal of devices through a single-lumen introducer sheath interrupts the infusion of medication at a controlled rate, which can be life threatening. Therefore, a single-lumen introducer sheath provides an inefficient means, at best, for the simultaneous passage of various devices and infusion of medication, particularly at a controlled rate.

Another possible solution is the use of a multi-lumen catheter. A problem with using a multi-lumen catheter is that the catheter is typically inserted into the vascular system through an introducer sheath. As a result, there is a time delay for initiating vascular access during the start-up of a procedure, which is particularly critical in an emergency or intensive care situation. Another problem with using a multi-lumen catheter is that the outside diameter of the catheter is significantly larger than that of a single-lumen catheter. As a result, a larger introducer sheath is used, and a larger opening is made in the patient's blood vessel. This large blood vessel opening causes a greater loss of blood and increased risk of complications that may be life threatening in surgical or emergency situations. Alternatively, if the outside diameter of a multi-lumen catheter is desirably small, the lumens of an elastic, soft plastic material catheter are also small, which severely limits the range of devices that can be passed through the catheter.

According to the present invention there is provided an introducer sheath as defined in claim 1.

The secondary lumen has a cross-sectional area significantly less than that of the main lumen for advantageously passing a relatively small dose of a fluid, such as a medication, therethrough. This advantageously allows small doses of medication to be injected without large "pushes" of another fluid such as saline to deliver the medication to the distal end of the sheath and the vascular system. Dead space in the lumen and proximal end fitting is minimized. Furthermore, medication can be infused at a controlled rate while another device, such as a guide wire or catheter, remains in, is inserted into, or is withdrawn from the main lumen of the introducer sheath.

The circular shape of the main lumen and the partially crescent shape of the secondary lumen maximizes the effective cross-sectional area of the introducer sheath while minimizing the outside diameter of the introducer sheath. The shapes of the lumens advantageously reduces the dead space of the secondary lumen of the introducer sheath while maximizing the inside diameter of the main lumen for passage of other medical devices therethrough.

The longitudinal axes of the hub main passage and the member main lumen are substantially parallel for readily introducing other devices therethrough and into the vascular system. The secondary lumen of the tubular member has a proximal opening recessed from the proximal end of the tubular member.

Brief Description of the Drawing

FIG. 1 depicts a partially-sectioned side view of a multiple lumen vascular access introducer sheath of the present invention;

FIG. 2 depicts an enlarged side view of the distal end of the sheath of FIG. 1 along the line 2-2; and

FIG. 3 depicts a cross-sectional view of the distal end of the sheath of FIG. 2 along the line 3-3.

Detailed Description

FIG. 1 depicts an illustrative multiple lumen vascular access introducer sheath 10 for the infusion of small doses of fluids, particularly at a controlled rate, and the introduction of medical devices such as catheters or wire guides therethrough and into the blood vessel of a patient. Sheath 10 comprises tubular member 11 with distal end 12, proximal end 13, and main lumen 14, which extends longitudinally therethrough and opens at the distal and proximal ends for positioning medical devices therein. Main lumen 14 has a generally circular and relatively large cross-sectional area for accommodating a range of medical devices and providing for the rapid delivery of large amounts of fluid such as saline, blood plasma, or whole blood. Tubular member 11 further includes secondary lumen 15, which is positioned adjacent main lumen 14 and is separated therefrom by inner wall 16. Secondary lumen 15 extends longitudinally through the tubular member from at least closed distal end 18 to proximal side port opening 17 that is cut or drilled near proximal end 13 of the tubular member. Secondary lumen 15 has an at least partially crescent shape and a significantly smaller cross-sectional area than that of the main lumen. The secondary lumen has a cross-sectional area comprising, for example, approximately 15 percent of that of the main lumen for minimizing dead space during injection of a predetermined dosage of fluid medication. Secondary lumen 15 opens distally at distal side port 19 formed in outer wall 20 of the tubular member, as depicted in FIG.2.

Tubular member 11 is formed of inelastic, semi-rigid plastic material 21 that includes a molten state such as nylon or fluorinated ethylene propylene. The molten state of the plastic material provides for taper 22 to be formed in distal end 12 of the tubular member for presenting an atraumatic surface to a blood vessel wall.

Sheath 10 further comprises hub 23 fixedly attached about proximal end 13 of the tubular member. Hub 23 comprises distal connector 28, intermediate connector 29, proximal Y-fitting 30, and lateral fitting 31. The distal connector and proximal Y-fitting are threadably attached and secured with a commercially available medical grade adhesive to the opposite ends of the intermediate connector. Hub 23 includes main passage 24, which extends through main arm 32 of the Y-fitting and has a longitudinal axis that is at least substantially parallel to the longitudinal axis of main lumen 14 of the tubular member. In this way, main lumen 14 communicates with main passage 24 for in-line introduction of devices and/or fluid therethrough. Main arm 32 includes male luer lock fitting 34 for lockable attachment to a syringe or another medical device and check valve 33 comprising, for example, a slotted silicone seal.

Hub 23 further includes side-arm passage 25 positioned in side arm 35 of Y-fitting 30 for communicating with main lumen 14 and extending laterally from the longitudinal axis of the main lumen. Side-arm passage 25 provides for the introduction of fluid into the main lumen of the tubular member when another medical device extends from the main lumen through main passage 24 of the hub. For convenient accessibility, extension tube 37 is positioned over side arm 35 and secured thereto by outer tubular connector 36, which is compression-fitted thereover. Extension tube 37 includes well-known male threaded connector 38 positioned at the proximal end thereof.

Hub 23 also further includes secondary passage 26 positioned in lateral fitting 31 and communicating with secondary lumen 15 via intermediate connector 29 and proximal opening 17. Secondary passage 26 extends laterally from the longitudinally axis of the main and secondary lumens of the tubular member. Lateral fitting 31 includes external threads about its distal end for being threadably affixed to intermediate connector 31. Extension tube 39 is positioned about the barbed outer surface of lateral fitting 31 and includes male luer lock fitting 40 about the proximal end thereof.

Distal O-ring 27 is positioned in intermediate connector 29 about outer wall 20 of the tubular member and distal to the intersection of secondary lumen 15 and secondary hub passage 26 for preventing leakage of fluid from the communicating passageways. Proximal O-ring 41 is positioned in intermediate connector 29 about the outer surface of the tubular member. Proximal O-ring 41 is sized smaller than the distal O-ring for compressing about the tubular member and collapsing the secondary lumen to prevent retrograde fluid flow and leakage from secondary lumen 15 and secondary hub passage 26. The proximal O-ring also facilitates retention of flared proximal end 13 of the tubular member in the intermediate connector.

Depicted in FIG. 2 is an enlarged side view of sheath 11 of FIG. 1 along the line 2-2 highlighting side port 19 of secondary lumen 15, which is formed in outer wall 20 of the tubular member. Taper 22 extending from distal end 12 is also shown.

Depicted in FIG. 3 is a cross-sectional view of sheath 11 of FIG. 2 along the line 3-3 with side port 19 positioned in outer wall 20 of the tubular member. Inner wall 16 separates relatively large, circular main lumen 14 and significantly smaller, crescent-shaped secondary lumen 15.

By way of example, sheath 10 accommodates an 8.5 French outside diameter catheter. Tubular member 11 is approximately 13cm long and 0.42 cms (.166") in diameter. Main lumen 14 is approximately 0.287cms (.113") in diameter, and secondary lumen 15 is approximately 0.076cms (.030") in minor diameter. Inner wall 16 is approximately 0.013cms (.005") thick, and outer wall 20 is minimally approximately 0.023 cms (.009") thick. Extension tube 37 is a plastic

material tube with an outside diameter of approximately 13 French (.170"). Extension tube 39 is a plastic material tube with an outside diameter of approximately 11 French (.144").

It is to be understood that the above-described vascular access introducer sheath is merely an illustrative embodiment of the principles of this invention and that other introducer sheaths may be devised by those skilled in the art. It is contemplated that the tubular member comprises any biocompatible semi-rigid material. It is further contemplated that the main and secondary lumens are sized larger or smaller or have other cross-sectional shapes such as square, rectangular, oval, elliptical, crescent, or a combination thereof for accommodating various other clinical applications. It is also further contemplated that other vascular access introducer sheaths include more than two lumens.

Claims

1. An introducer sheath (10) comprising
a tubular member (11) of biocompatible inelastic material with a main lumen (14) extending longitudinally therethrough and having a cross-sectional area sufficient to enable a surgical instrument and/or relatively large amount of fluid to be passed therethrough, CHARACTERISED IN THAT the tubular member also has a secondary lumen (15) positioned adjacent to and separated from said main lumen, and having a cross-sectional area sufficiently smaller than the cross-sectional area of said main lumen in order to facilitate passage of a relatively smaller amount of fluid therethrough.

2. The sheath of claim 1 wherein said tubular member includes an outer wall and wherein said secondary lumen is closed at said distal end of said tubular member and includes a side port in said outer wall near said distal end of said tubular member.

3. The sheath of claim 1 or 2, further comprising a hub (23) attached to the proximal end of said tubular member and having a main passage (24) extending longitudinally through the hub and communicating with said main lumen, said main passage of said hub having a longitudinal axis in alignment with or parallel to the longitudinal axis of said main lumen.

4. The sheath of claim 3, wherein said secondary lumen has an opening (17) recessed from the proximal end of the tubular member, and/or the hub has a secondary passage (26) communicating with the secondary lumen and extending laterally from said secondary lumen.

5. The sheath of claim 4 wherein said hub has a third passage communicating with said main lumen.

6. The sheath of claim 1 wherein said cross-sectional area of said main lumen is circular, and wherein said secondary lumen has at least a partially crescent shape.

7. The sheath of any one preceding claim, wherein said tubular member has an inner wall separating said main and secondary lumens.

8. The sheath of any one preceding claim, wherein the cross-sectional area of said secondary lumen is approximately fifteen percent of the cross-sectional area of said main lumen.

9. The sheath of any one preceding claim, wherein the tubular member is of fluorinated ethylene propylene or nylon.

10. The sheath of any one preceding claim, wherein the tubular member has a tapered distal end.

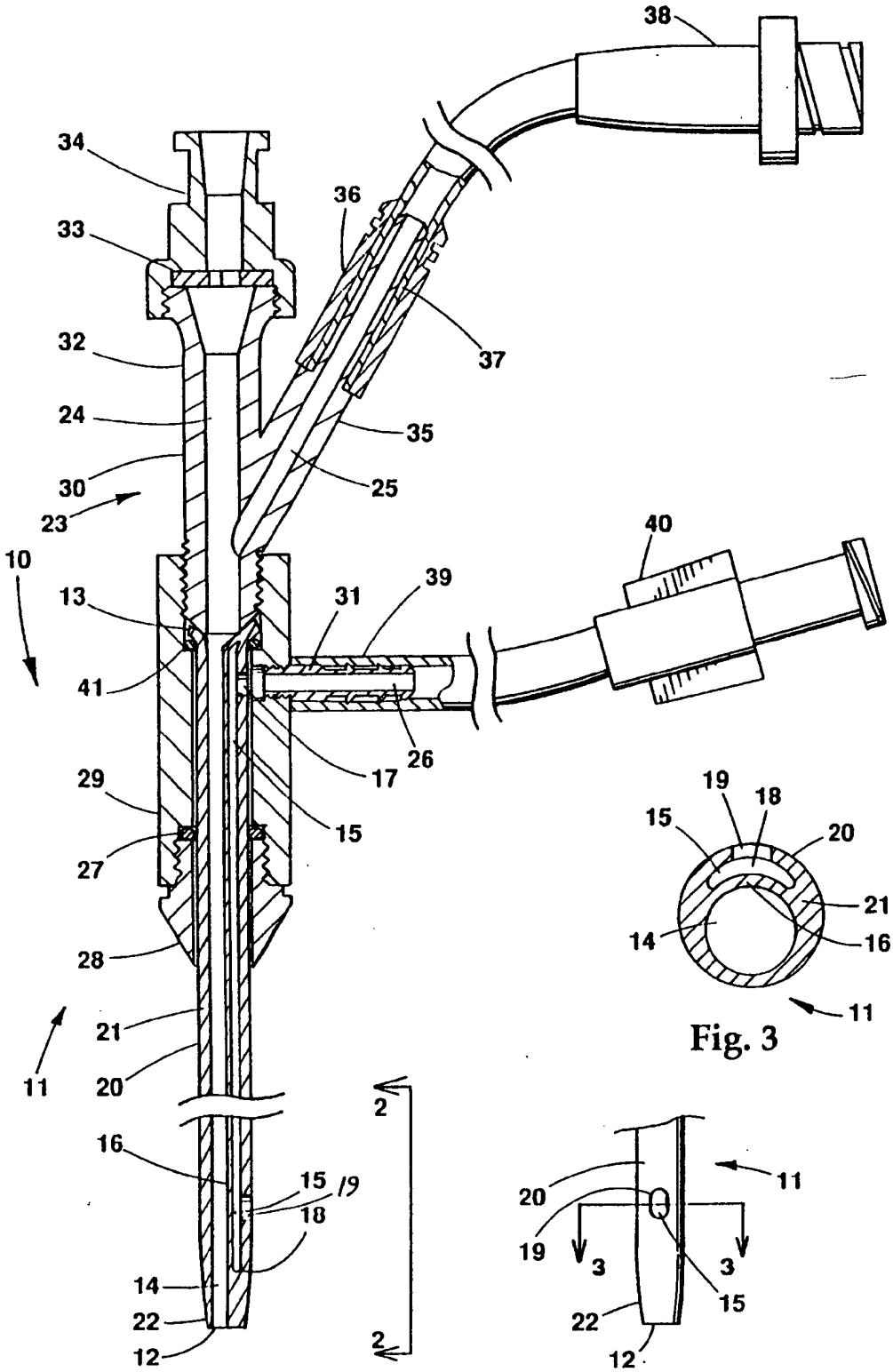

Fig. 1

Fig. 3

Fig. 2

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EUROPEAN SEARCH REPORT

Application Number
EP 93 30 7771

DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int.Cl.5)
X Y A	EP-A-0 465 458 (SKRABAL) 8 January 1992 * page 4, line 25 - page 5, line 13; figures 1-4A * * abstract *	1,3-7 2,9,10 8	A61M5/00 A61M25/00 A61M39/02
Y	EP-A-0 504 934 (MARTIN) 23 September 1992 * column 3, line 11 - line 53; figures 1-4 *	2,10	
Y	US-A-5 149 330 (BRIGHTBILL) 22 September 1992 * column 3, line 38 - line 42; figure 1 *	9	
A	EP-A-0 306 010 (DANFORTH) 8 March 1989 * ; figures 1-5 *	1-9	
A	US-A-4 014 333 (MCINTIRE) 29 March 1977 * abstract; figures 1-8 *	1-10	
A	EP-A-0 495 263 (KENDALL) 22 July 1992 * abstract; figures 1-4 *	1-10	

TECHNICAL FIELDS SEARCHED (Int.Cl.5)

A61M

The present search report has been drawn up for all claims

Place of search	Date of completion of the search	Examiner
MUNICH	5 January 1995	Germano, A

CATEGORY OF CITED DOCUMENTS

X : particularly relevant if taken alone
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